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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,126	12/06/2000	Sheng C. Lou	6755.US.O1	9182
23492	7590	01/28/2004	EXAMINER	
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/731,126

## Applicant(s)

LOU ET AL.

## Examiner

Jeffrey S. Parkin, Ph.D.

## Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) N/A.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Docket No.: 6755.US.01  
Filing Date: 12/06/00

### Detailed Office Action

#### *Status of the Claims*

1. Applicants' election with traverse of Group VII (claims 5-16 and the Mabs 120A-270, 115B-151, and 115B-303) is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Applicants are advised that upon perusal of the disclosure and a review of the prior art the Examiner has decided to rejoin the additional Mabs (e.g., 117-289, 103-350, and 108-394) set forth in the originally filed claims. Claims 1-4 and 17-28 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

#### *Information Disclosure Statement*

2. The information disclosure statements filed 09 April, 2001, and 03 February, 2003, have been placed in the application file and the information referred to therein has been considered.

#### *Disclosure*

3. The disclosure is objected to because of the following informalities: page 17 of the disclosure references various deposited hybridoma cell lines but fails to provide the ATCC numbers. Appropriate correction is required.

#### *35 U.S.C. § 112, First Paragraph*

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the

best mode contemplated by the inventor of carrying out his invention.

5        5. Claims 6, 9-12, and 14-16 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. It is apparent that the claimed Mabs are required to practice the claimed invention. As a required element they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.  
10        If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the hybridoma cell line producing said Mab. See 37 C.F.R. § 1.802.

15        Due to the well-documented nature of the generation of antibody diversity, and in the absence of any detailed structural information pertaining to any given Mab, the specification clearly fails to provide a repeatable method for obtaining any particular Mab. Moreover, the various Mabs claimed do not appear to be readily available materials. Accordingly, a deposit of the  
20        hybridoma cell line produced said Mabs would satisfy the enablement requirements of 35 U.S.C. § 112. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of  
25        record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.  
30        See 37 C.F.R. § 1.808.

      If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to

make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

5 (a) during the pendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;

10 (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

15 (c) the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

20 (d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

25 In addition, the identifying information set forth in 37 C.F.R. § 1.809(d) should be added to the specification. See 37 C.F.R. §§ 1.803-1.809 for additional explanation of these requirements.

**35 U.S.C. § 112, Second Paragraph**

30 6. Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim references Mab 120-270 when it appears to actually reference Mab 120A-270. Appropriate correction is  
35 required.

**35 U.S.C. § 102**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this

section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 5, 8, and 13 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Butman and Venetta (1996). This teaching discloses Mabs (including labeled conjugates) that recognize the capsid antigens of both HIV-1 and -2 and detection assays employing said Mabs.

***Allowable Subject Matter***

9. Detection methods employing the specific Mabs (e.g., 120A-270, 115B-151, 117-289, 103-350, 115B-303, and 108-394) appear to be free of the prior art and would be allowable provided the biological deposit guidelines are met. Applicants should amend the claim language to reflect the deposit information when obtained (i.e., A method for detecting ... wherein at least one monoclonal antibody is selected from the group consisting of 120A-270, 115B-151, ...).

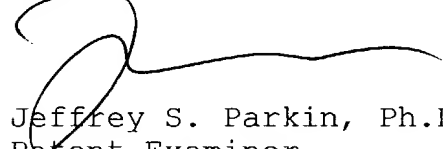
***Correspondence***

10. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

A handwritten signature in black ink, appearing to read 'Jeffrey S. Parkin', with a large, stylized loop at the beginning.

Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

24 January, 2004